

<b>Case Number:</b>	CM15-0197946		
<b>Date Assigned:</b>	10/13/2015	<b>Date of Injury:</b>	12/17/1999
<b>Decision Date:</b>	12/03/2015	<b>UR Denial Date:</b>	10/05/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/08/2015

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:  
 State(s) of Licensure: California  
 Certification(s)/Specialty: Family Practice

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 60 year old female who sustained an industrial injury on 12-17-99. A review of the medical records indicates she is undergoing treatment for pain in joint - shoulder region and reflex sympathetic dystrophy of the upper limb. Medical records (9-24-15) indicate ongoing complaints of left shoulder and arm pain, which increases with "any use". The record indicates "no major changes in the left shoulder and arm pain" and "current medications are working well". She also reports that the quality of her sleep "remains poor", noting difficulty falling asleep and maintaining sleep. The record reflects that a "prepsyche eval" was completed for a spinal cord stimulator. She rates her pain, on average, "7 out of 10". The physical exam reveals "ongoing baseline pain" in her left shoulder with decreased range of motion due to pain. The treating provider states, "there is still pain down her left arm but was decreased after cervical epidural steroid injection". Treatment includes medications: Aciphex, Celebrex, Fentanyl patches, Fentora, and Morphine. She has been receiving all medications since, at least, 3-31-15. The utilization review (10-5-15) includes a request for authorization of Fentora 400mcg, 1 daily as needed for severe break through pain #28. The determination was to modify this to Fentora 200mcg, 1 daily as needed for severe break through pain #28.

### IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

**Fentora 400mg #28:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter; ACOEM Chapter 7-Independent Medical Examinations and Consultations, page 127.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Fentora (fentanyl buccal tablet). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/ Fentora.

**Decision rationale:** According to MTUS and ODG, Fentora (fentanyl buccal tablet) is not recommended for musculoskeletal pain. Fentora is an opioid painkiller currently approved for the treatment of breakthrough pain in certain cancer patients. Cephalon had applied to the FDA for approval to market the drug for patients with other pain conditions such as chronic low back pain and chronic neuropathic pain, but approval was not obtained. The medical records do not indicate that the injured worker is being treated for cancer breakthrough pain and therefore the request for Fentora is not supported by the MTUS and Official Disability Guidelines. The medical records note that Utilization Review has allowed for modification for weaning of Fentora. The request for Fentora 400mg #28 is not medically necessary and appropriate.